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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.                    | CONFIRMATION NO. |
|--|-------------|----------------------|--|------------------|
| 09/676,032   | 09/29/2000  | Joseph K. Agyin      | 6643R5                                 | 3249             |
| 27683  | 7590        | 05/25/2004           |  |                  |
| HAYNES AND BOONE, LLP<br>901 MAIN STREET, SUITE 3100<br>DALLAS, TX 75202 |             |                      | EXAMINER<br>DELACROIX MUIRHEI, CYBILLE |                  |
|  |             |                      | ART UNIT                               | PAPER NUMBER     |
|  |             |                      | 1614                                   |                  |

DATE MAILED: 05/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

### Application No.

09/676,032

### Applicant(s)

AGYIN ET AL.

### Examiner

Cybille Delacroix-Muirheid

### Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4,7-11,13-15,20 and 25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4,7-11,13-15,20 and 25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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### ***Detailed Action***

The following is responsive to Applicant's amendment received Dec. 17, 2003.

Claims 5-6, 12, 16-19, 21-24 are cancelled. No new claims are added. Claims 1-4, 7-11, 13-15, 20 and 25 are currently pending.

The previous rejection of claim 25 under 35 USC 112, paragraph 1, set forth at pages 4-7 of the office action mailed Sep. 19, 2003 **is withdrawn** in view of Applicant's amendment and the remarks contained therein.

The previous claim rejection under 35 USC 103(a) set forth in paragraphs 2-4 of the office action mailed Aug. 27, 2002 and maintained in the final rejection mailed March 17, 2003 **is withdrawn** in view of Applicant's amendment and the remarks contained therein.

### ***New Ground(s) of Rejection***

#### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 1-4, 7-11, 13-15, 20 and 25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 18-20 of U.S. Patent No. 6,482,843. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant application and USPN '843 claim benzimidazole derivatives represented by formulae A-3 and A-1, respectively, and pharmaceutical compositions thereof. The difference between the instant application and USPN '843 is that USPN '843 claims a benzimidazole compound wherein the "COOR1" group for substituent "R" is located at a different carbon on the benzene ring.

However, the compound of the instant application is obvious over the compound claimed in USPN '843 because it is a positional isomer and the compound of USPN '843, being so structurally similar, suggests the claimed compound of the instant invention. The compounds of both the instant application and USPN' 843 would be expected to share common properties.

Additionally, the scope of the claims of the instant application and the claims of USPN '843 overlaps because at least one of the moieties listed for substituent "R", i.e. "COOR1" and substituent "R1" is identical. Furthermore, the compound claims of the instant application are obvious in view of the pharmaceutical composition claims in USPN '843.

Finally, it would have been obvious to one of ordinary skill in the art to modify the pharmaceutical compositions into a kit by including instructional materials for pharmaceutical use because the inclusion of instructional material is widely used in the

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art and is therefore within the capability of the skilled artisan. Also, instructional material only pertains to the intended use of the composition and does not distinguish the actual composition of the instant application from the composition of USPN '843.

**Conclusion**

Claims 1-4, 7-11, 13-15, 20 and 25 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is 571-272-0572. The examiner can normally be reached on Mon-Fri from 9:30 to 6:00.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached at 571-272-0584. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CDM



May 16, 2004



Cybille Delacroix-Muirheid  
Patent Examiner Group 1600